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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/057,832 | 01/25/2002 | Max Costa | 5986/11147US1 | 1550 |
| 7278 | 7590 | 06/28/2005 | EXAMINER | |
| DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257 | | | UNGAR, SUSAN NMN | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1642 | |
| DATE MAILED: 06/28/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/057,832

Applicant(s)

COSTA ET AL.

Examiner

Susan Ungar

Art Unit

1642

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 January 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on 27 April 2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☒ They raise the issue of new matter (see NOTE below);
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

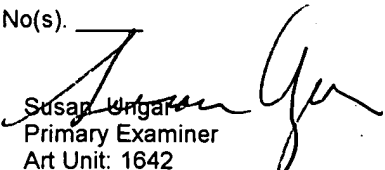
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: _____.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____


Susan Ungar
Primary Examiner
Art Unit: 1642

Continuation of 3. NOTE: The new issues raised are drawn to CAP43 polypeptides comprising amino acid sequence at least 70% identical to SEQ ID NO:2 and expressed at elevated levels in cancer cells.

The new matter is drawn to polypeptides with 70% identity to CAP43 and expressed at elevated levels in cancer cells. A review of the specification and the cited support did not reveal any nexus between overexpression and a polypeptide with 70% identity to SEQ ID NO:2.

Continuation of 11. does NOT place the application in condition for allowance because: If the Amendment were to be entered, Claims 1-7, 10, 25-33, 35, 51 and 55 would remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the Paper mailed October 28, 2004.

Applicant submits that claims 52 and 56 have not been canceled by Applicants. Applicant is correct, claims 52 and 56 were inadvertently left out of the rejections under 35 USC 112 first paragraph, Written Description, and 35 USC 102(f). It is noted that Applicant does not suggest that in view of this that the claims should be allowable. Thus it is clear that Applicant is aware that the claims are not allowable and rejected under those statutes and that the issues remain the same. Examiner appreciates Applicant pointing out the inadvertent typographical error. It is noted that as drawn to the rejection under 35 USC 102(f), it appears that the petition to correct inventorship will be acceptable to the Office and thus the inclusion or lack thereof of claims 52 and 56 in the rejection in the Final Action is rendered moot.

Applicant reiterates arguments that the features of CAP43 proteins and nucleic acids that are relevant to this invention are fully described. The arguments have been considered but have not been found persuasive for the reasons of record.

Applicant has amended the claims, specifically independent claims 1 and 25 to specify that CAP43 comprises an amino acid sequence at least 70% identical to the exemplary human CAP43 amino acid sequence, SEQ ID NO:2 and is expressed at elevated levels and has limited claims 51 and 55 to SEQ ID NO:2 and new dependent claims 103-106 particularly specify that CAP43 is encoded by the preferred full length, human CAP43 nucleotide sequence, SEQ ID NO:1 and thus the application complies with the written description requirement. The argument has been considered but has not been found persuasive because, as drawn to the 70% limitation, of the reasons of record. Further, as drawn to SEQ ID NO:1, the claims have not in fact been entered.

If the Amendment were to be entered, claims 1-7, 25-33, 51, 55 would remain rejected under 35 USC 102(e) for the reasons of record.

Applicant argues that the Adams reference does not specifically state that the diagnostic methods include the diagnosis of cancer. The argument has been considered but has not been found persuasive because a review of the reference reveals, as set forth in the first action on the merits that the diagnostic methods of the reference apply to cancer, Applicant is invited to review page 15 of the first action on the merits and to review column 7 of the reference. By selectively reciting the teachings of the reference, Applicant is mischaracterizing the teaching of the reference. Although the reference does indeed state that it relates to methods for diagnosing hypoxia or a vascular or circulatory condition associated with a reduction in blood flow in column 7, the reference goes on to define the conditions associated with reduction in blood flow and includes cancer in that list. Although the patent goes on to state that the invention contemplates the diagnosis of altered vasculature resulting in hypoxia within tumors, this does not alter the fact that included in the vascular conditions associated with reduction in blood flow that are diagnosed is cancer. Applicant further argues that at best the Adams patent actually describes a method for identifying and/or diagnosing hypoxia by detecting up-regulation of the RTP/DRG1 gene. The argument has been considered but has not been found persuasive because for the reasons previously set forth, the claimed invention is anticipated by the referenced patent. Applicant reiterates arguments that the referenced patent actually teaches away and reiterates from the claimed invention and points to Example 3. The argument has been considered but has not been found persuasive for the reasons of record. Although Applicant states that no evidence is provided drawn to the differences between cells in vitro and in vivo. It is noted however, that Applicant does not argue that Examiner is not correct. Further, Applicant calls into question the enablement of the referenced patent. Applicant is reminded that issued United States Patents are enabling.

If the Petition to Correct Inventorship is acceptable, the rejection of the claims under 35 USC 102(f) will be moot.